UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Plaintiff

v.

SHIRE VIROPHARMA INC.
300 Shire Way
Lexington, MA 02421

Defendant.

Case Number:

Complaint for Injunctive and Other Equitable Relief

Plaintiff, the Federal Trade Commission ("FTC"), by its designated attorneys, petitions this Court, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), for a permanent injunction and other equitable relief against Defendant Shire ViroPharma Inc. ("ViroPharma"), to redress and prevent unfair methods of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

I. NATURE OF THE CASE

1. This antitrust case challenges ViroPharma's abuse of the U.S. Food and Drug Administration's ("FDA") citizen petition process to maintain its monopoly on Vancocin Capsules, a drug used to treat a potentially life-threatening gastrointestinal infection. Facing the threat of generic competition to its lucrative franchise, ViroPharma inundated the FDA with regulatory and court filings—forty-six in all—to delay the FDA's approval of generic Vancocin Capsules. That number is, by far, the most filings that any firm has ever made to the FDA

concerning a single drug product. These repetitive, serial, and meritless filings lacked any supporting clinical data, which ViroPharma understood it needed to have any chance of persuading the FDA of its positions. Even after a panel of sixteen independent experts unanimously rejected its unsupported claims in August 2009, ViroPharma continued its petitioning campaign to obstruct and delay the FDA's generic approval review process. Ultimately, in April 2012, the FDA disposed of ViroPharma's challenges as being "unsupported" and "lack[ing] merit." But by that point, ViroPharma's campaign had succeeded in delaying generic entry at a cost of hundreds of millions of dollars to patients and other purchasers.

II. JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b) and 28 U.S.C. §§ 1331, 1337(a), and 1345.

3. This Court has personal jurisdiction over the Defendant pursuant to 15 U.S.C. § 53(b) and because the Defendant has the requisite constitutional contacts with the United States of America and the state of Delaware.

4. Venue in this district is proper under 15 U.S.C. § 22, 28 U.S.C. § 1391(b) and (c), and 15 U.S.C. § 53(b). The Defendant resides, transacts business, committed an illegal or tortious act, or is found in this District.

5. The Defendant's general business practices, and the unfair methods of competition alleged herein, are "in or affecting commerce" within the meaning of Section 5 of the FTC Act, 15 U.S.C. § 45.

6. The Defendant is, and at all relevant times has been, a corporation, as the term "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

III. THE PARTIES

7. Plaintiff FTC is an administrative agency of the United States Government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41, *et seq.*, with its principal offices in the District of Columbia. The FTC is vested with authority and responsibility for enforcing, *inter alia*, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to enjoin violations of any law the FTC enforces and to seek equitable monetary remedies.

8. Defendant Shire ViroPharma Inc. is a for-profit Delaware corporation, with its principal place of business at 300 Shire Way, Lexington, Massachusetts 02421. Except where otherwise specified, "ViroPharma" refers to Shire ViroPharma Inc. and all corporate predecessors, subsidiaries, successors, and affiliates. ViroPharma is engaged in the business of, among other things, developing, manufacturing, and marketing branded drug products, including *inter alia*, Cinryze.

IV. REGULATORY BACKGROUND

A. The Pharmaceutical Regulatory System Facilitates Competition from Generic Drugs.

9. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 335(b)(2) and 355(j), and 35 U.S.C. § 271(e), establishes procedures designed to facilitate and speed competition in prescription drug markets from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.

10. A company seeking to market a new pharmaceutical product in the United States must file a "New Drug Application" ("NDA") with the FDA, demonstrating the safety and efficacy of the product. Products approved following submission of an NDA are referred to as "brand-name drugs" or "branded drugs."

11. Generally, a company demonstrates the safety and efficacy of a proposed branded drug using data derived from in vivo clinical endpoint studies. A clinical endpoint study typically involves hundreds of sick patients. In the study, researchers provide some of the sick patients with the proposed drug and others with a placebo and then compare the safety and efficacy of the proposed drug to the placebo.

12. Once the FDA has approved an NDA, the manufacturer may file a supplemental New Drug Application ("sNDA") to seek approval for a change to its branded drug or the branded drug's label.

13. A company seeking to market a generic drug may file an Abbreviated New Drug Application ("ANDA") with the FDA. The ANDA applicant is not required to demonstrate the safety and efficacy of the proposed generic drug. Instead, it may rely on the approved branded drug's profile for safety and efficacy.

14. An ANDA applicant must, however, demonstrate that its proposed generic drug is bioequivalent to the approved branded drug that it references and for which it seeks to be a generic substitute. Bioequivalence is defined as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalences or pharmaceutical alternatives becomes available at the site of drug action . . . ." 21 C.F.R. § 314.3; *see also* 21 C.F.R. § 320.1.

15. The FDA assigns a generic drug an "AB" rating if it is therapeutically equivalent to the branded drug. An AB-rated generic drug is the same as a branded drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

B. The FDA Has Wide Discretion To Establish the Appropriate Method of Demonstrating Bioequivalence.

16. The FDCA and applicable federal regulations grant the FDA considerable flexibility in determining how a manufacturer may establish that its generic drug is bioequivalent to a branded drug. For example, Section 505(j)(8)(C) of the FDCA provides that the "Secretary may establish alternative, scientifically valid methods to show bioequivalence" for those drugs (like Vancocin Capsules) that are "not intended to be absorbed into the bloodstream." Such methods include using in vivo or in vitro testing. The FDA's own regulations likewise reflect its flexibility in choosing the appropriate methods to establish bioequivalence for particular drug products. For example, 21 C.F.R. § 320.24(a) states that the "FDA may require in vivo or in vitro testing" and that the "selection of the method used . . . depends upon the purpose of the study, the analytical methods available, and the nature of the drug product."

17. The FDA's authority to make bioequivalence determinations on a case-by-case basis using in vivo or in vitro testing enables the FDA to effectuate several long-recognized policies that protect the public health: (1) refraining from unnecessary human research when other methods of demonstrating bioequivalence meet the statutory and regulatory standards; (2) permitting the FDA to use scientific advances in approving drug products; (3) protecting the public by ensuring only safe and effective generic drugs are approved for marketing; and (4) making more safe and effective generic drugs available.

C. The Citizen Petition Process May Be Abused to Delay FDA Approval of Generic Drugs.

18. A citizen petition is a request that the FDA "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.30(b)(3). A citizen petition is a public document that may be supplemented or amended by the petitioner. In a supplement, a petitioner may add requests to the FDA. In an amendment, a petitioner may amend its requests to the FDA.

19. The manufacturer of a branded drug may file a citizen petition in anticipation of or in response to an ANDA from a generic drug manufacturer.

20. The FDA must review and respond to every citizen petition it receives, including any supplements and amendments. 21 C.F.R. § 10.30(e)(1). Citizen petition filings by a brand company can raise issues related to generic applications and the criteria that the FDA should use to review and approve those generic applications. The FDA generally follows the same process with respect to issues and arguments raised in amendments and supplements to citizen petitions. Hence, the FDA generally resolves and responds to issues and arguments raised by citizen petition filings, including supplements and amendments, before or at the same time it approves a generic application.

21. In 2007, after ViroPharma made its first citizen petition filing regarding generic Vancocin Capsules, Congress amended Section 505 of the FDCA to try to curb the potential delaying effect of citizen petitions. As one Senate sponsor recognized in discussing the scope of the problem, "the simple act of filing a petition, no matter how meritorious or frivolous that petition may be, automatically delays the approval of a generic drug."

22. Section 505(q) of the FDCA requires the FDA to respond to citizen petitions within a specified time-period and prohibits the FDA from delaying the approval of an ANDA despite a pending citizen petition unless "the [FDA] determines, upon reviewing the petition, that a delay is necessary to protect the public health." But Section 505(q) applies only to citizen petitions filed in September 2007 or later. Therefore, ViroPharma's initial citizen petition filing in March 2006, and its supplement and amendment filings were not subject to Section 505(q).

23. Section 505(q) has not eliminated the ability of branded drug companies to try to use the citizen petition process to delay the entry of generics. In annual reports to Congress regarding Section 505(q), the FDA has reported that the "FDA continues to be concerned that Section 505(q) is not discouraging the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues." The FDA has raised particular concern about "serial petitions." Serial petitions target the same specific drug or class of drugs, often come from the same petitioner, and sometimes require the FDA to issue several separate responses. The FDA has noted its belief that branded drug companies are "implementing strategies to file serial [petitions] in an effort to delay approval of ANDAs . . . for competing drugs."

24. The FDA has limited resources and means for dealing with serial petitioning. As the FDA has observed, "[r]esponding to such serial petitions requires the use of substantial FDA resources, on a repeated basis, over a protracted period of time."

V. GENERIC DRUG COMPETITION BENEFITS CONSUMER WELFARE

A. State Law Encourages Substitution of AB-Rated Generic Drugs for Branded Drugs.

25. All fifty states and the District of Columbia have drug substitution laws that encourage and facilitate the substitution of lower-cost AB-rated generic drugs for branded drugs.

When a pharmacist fills a prescription written for a branded drug, these laws allow or, in some instances, require the pharmacist to dispense a lower-priced AB-rated generic version of the branded drug, unless a physician directs or the patient requests otherwise.

26. State substitution laws were enacted in part to lower health care costs. In the prescription drug market, a patient can lawfully obtain a prescription drug only if a doctor writes a prescription for that particular drug. The doctor who selects the drug, however, does not pay for it and generally has little incentive to consider price when deciding which drug to prescribe. Instead, the patient, or in most cases a third-party payer such as a public or private health insurer, pays for the drug. Unlike in most markets, where a consumer selects and pays for a product after evaluating the product's price and quality, consumers of health care products may have little input over what drug is prescribed.

27. State substitution laws are designed to correct this market imperfection by shifting the drug selection choice, when a generic is available, from physicians to pharmacists and patients who have greater financial incentives to make price comparisons.

B. Competition from Lower-Priced Generic Drugs Saves American Consumers Billions of Dollars Every Year.

28. The Hatch-Waxman Act and state substitution laws have succeeded in facilitating and advancing generic competition, generating large savings for patients, health care plans, and federal and state governments. The first generic competitor's product typically is offered at a 20% to 30% discount to the branded drug. Subsequent generic entry creates greater price competition with discounts reaching 85% or more off the branded drug's price. According to a 2010 Congressional Budget Office report, the retail price of a generic is 75% lower, on average, than the retail price of a branded drug. In 2015 alone, the Generic Pharmaceutical Association reported that use of generic versions of branded drugs saved the U.S. health care system

$227 billion.

29. Because of these price advantages and cost savings, many third-party payers of prescription drugs (e.g., health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. As a result, many consumers routinely switch from a branded drug to a lower-priced AB-rated generic drug upon its introduction. Consequently, within six months of market entry, AB-rated generic drugs typically capture over 80% of a branded drug's unit and dollar sales.

VI. FACTUAL BACKGROUND

A. The FDA Did Not Require In Vivo Clinical Endpoint Studies When It Approved Vancocin Capsules.

30. Vancocin Capsules are an oral antibiotic indicated to treat *Clostridium difficile*-associated diarrhea ("CDAD"), a serious and potentially life-threatening gastrointestinal infection.

31. Vancocin Capsules are a locally-acting, non-systemically absorbed drug. This means that when ingested orally, the active ingredient, vancomycin hydrochloride, does not move across the gastrointestinal tract wall into the bloodstream or general circulation. Instead, once a patient swallows a Vancocin Capsule, it dissolves rapidly, releasing the active ingredient vancomycin hydrochloride, which mixes with gastrointestinal fluids and travels through the gastrointestinal tract, targeting and killing the *C. difficile* bacteria.

32. Vancocin Capsules were developed as a substitute to Vancocin Oral Solution, which contains the same active ingredient and has the same route of administration and indications as Vancocin Capsules. Some patients, however, could not tolerate the taste of Vancocin Oral Solution. In response, Eli Lilly, the manufacturer of Vancocin Oral Solution, developed an encapsulated form of the product.

33. On March 15, 1985, Eli Lilly submitted an NDA for Vancocin Capsules to the FDA. The NDA for Vancocin Capsules did not include clinical endpoint studies. Instead, Eli Lilly asserted that the Vancocin Capsules were "an alternative, more convenient delivery system" to Vancocin Oral Solution, an already approved drug that the FDA knew was safe and effective.

34. The NDA for Vancocin Capsules included in vitro dissolution data for Vancocin Capsules and comparative in vivo pharmacokinetic data of Vancocin Capsules and Vancocin Oral Solution (measuring vancomycin hydrochloride in blood, urine, and feces samples) in twelve healthy people. With the in vitro dissolution data of Vancocin Capsules, Eli Lilly demonstrated that Vancocin Capsules dissolved rapidly such that vancomycin hydrochloride was available at levels comparable to Vancocin Oral Solution. With the comparative in vivo pharmacokinetic data, Eli Lilly showed that little to no vancomycin hydrochloride was absorbed into the bloodstream or general circulation.

35. In vivo pharmacokinetic studies are distinct from in vivo clinical endpoint studies. The former analyzes absorption of drugs in healthy subjects while the later analyzes the safety and efficacy of drugs in sick patients.

36. On April 15, 1986, the FDA approved the NDA for Vancocin Capsules based on in vitro dissolution data.

B. Shortly After Acquiring Vancocin Capsules, ViroPharma Significantly Raised Its Price.

37. ViroPharma acquired the rights to Vancocin Capsules from Eli Lilly in November 2004. At that time, ViroPharma was a small branded pharmaceutical company. It did not have any drugs on the market and had not completed the development of, or received regulatory

approval for, any of the products in its pipeline. Since its formation in 1994, ViroPharma had failed to produce a profit and had only incurred losses.

38. From 2004 through 2011, Vancocin Capsules was ViroPharma's largest revenue generating product, accounting for all of the company's total net revenues until 2009 and up to 53% of the company's total net revenues in 2011. U.S. sales for Vancocin Capsules grew from about $40 million in 2003 to almost $300 million by 2011.

39. As part of its due diligence before purchasing the rights to Vancocin Capsules, ViroPharma commissioned a study to examine the price elasticity and sensitivity of the market. In the study, ViroPharma's pricing consultant recommended multiple price increases of Vancocin Capsules to consumers and payers. The study noted that ViroPharma could successfully implement multiple price increases because the market was small enough that it was not actively monitored and because "[b]y the time these patients are on Oral Vancocin, they *need* it."

40. ViroPharma's internal documents demonstrate that it recognized that Vancocin Capsules were a "sole source item" in that it faced "no competition in its current space" as a life-saving drug for CDAD.

41. After acquiring the rights to Vancocin Capsules, ViroPharma regularly and significantly raised Vancocin Capsules' price to consumers and payers. In 2004, the average wholesale prices of Vancocin Capsules in the 125 mg and 250 mg strengths were $6.38 and $12.73, respectively. By 2011, the year before generic entry, ViroPharma had increased those average wholesale prices by almost 300% to $24.61 and $46.48, respectively. Over that same period, unit sales of Vancocin Capsules in the 125 and 250 mg strengths increased by 37% and 39%, respectively.

C. Generic Competition Threatened ViroPharma's Vancocin Capsules Monopoly.

42. The financial success of Vancocin Capsules began to draw the attention of generic companies. The product was particularly vulnerable to generic competition because it was an old product with no patent protection or other regulatory exclusivities. The primary barrier to generic competition was the FDA's then-existing recommendation that companies seeking to develop generic versions of Vancocin Capsules conduct expensive and time-consuming in vivo clinical endpoint studies to demonstrate bioequivalence.

43. By the time ViroPharma purchased Vancocin Capsules, however, the FDA had started to reconsider this guidance. In October 2004, the FDA convened a public meeting of the Advisory Committee for Pharmaceutical Science ("Advisory Committee"), an independent panel of experts that provides advice to the FDA, to discuss bioequivalence testing for non-absorbing locally-acting gastrointestinal drugs like Vancocin Capsules. Although the Advisory Committee did not specifically discuss Vancocin Capsules, it spoke approvingly of in vitro dissolution testing for non-absorbing locally-acting gastrointestinal drugs.

44. ViroPharma grew increasingly concerned that the FDA might permit generic applicants to establish bioequivalence to Vancocin Capsules through in vitro dissolution data instead of in vivo clinical endpoint studies. For example, in October 2005, ViroPharma's Director of Regulatory Affairs confirmed to ViroPharma's Chief Executive Officer and other executives that "[f]or approval of any generic product, the FDA may require in vivo studies, in vitro studies, or both depending on the nature of the drug, the analytical methods available and the purpose of the study," mirroring the language of 21 C.F.R. § 320.24.

45. By November 2005, ViroPharma hired a bioequivalence consultant, Nicholas Fleischer, Ph.D., a former Director of the FDA's Division of Bioequivalence in the Office of

Generic Drugs, to advise it on what bioequivalence testing the FDA might require from companies seeking approval for a generic version of Vancocin Capsules. Dr. Fleischer informed ViroPharma in November 2005 that the FDA was not requiring in vivo clinical endpoint studies to establish bioequivalence to non-absorbing oral gastrointestinal drugs, and that the FDA would likely allow generics to submit in vitro dissolution data to establish bioequivalence to Vancocin Capsules. Dr. Fleischer advised ViroPharma that it should submit a citizen petition or controlled correspondence "sooner than later." He also expressly informed ViroPharma that without at least supporting clinical data it could not convince the FDA of its position against use of in vitro dissolution testing.

46. By December 2005, ViroPharma had drafted a controlled correspondence requesting that the FDA continue to recommend that generic applicants of Vancocin Capsules conduct in vivo clinical endpoint studies to establish bioequivalence. When Dr. Fleischer reviewed this correspondence, he noted the lack of supporting clinical data and reiterated his previous advice that such data were critical to convince the FDA: "As was stated during our telecom, this document will serve the purpose of getting something in front of the Agency very fast but it is not a very convincing 'story' without data and references."

D. In February 2006, the FDA Advised That It Would Accept In Vitro Dissolution Data for Establishing Bioequivalence to Vancocin Capsules.

47. Following the October 2004 meeting of the Advisory Committee, Akorn, a manufacturer of generic drugs, requested the FDA's guidance regarding bioequivalence as to generic Vancocin Capsules. In February 2006, the FDA advised Akorn that bioequivalence could be established through in vitro dissolution testing. The FDA shared this guidance with other manufacturers of generic drugs that inquired.

48. Akorn submitted its ANDA for Vancocin Capsules to the FDA on March 5, 2007. Two other generic applicants, Strides, Inc. and Watson Laboratories, Inc., submitted their ANDAs on May 1 and September 28, 2007, respectively. The FDA eventually approved all three ANDAs on April 9, 2012, the same day it finally disposed of all of ViroPharma's citizen petition filings.

VII. VIROPHARMA ENGAGED IN UNLAWFUL EXCLUSIONARY CONDUCT BY MAKING DOZENS OF FILINGS BEFORE THE FDA AND BY FILING THREE SEPARATE FEDERAL LAWSUITS AGAINST THE FDA

49. Between March 2006 and April 2012, ViroPharma made at least forty-three submissions to the FDA and initiated three more proceedings in federal court to obstruct and delay the FDA's approval of generic Vancocin Capsules, including:

- Twenty-four citizen petition filings submitted to the FDA;
- Seventeen public comments submitted to the FDA regarding the FDA's in vitro dissolution guidance for generic Vancocin Capsules;
- A public comment submitted to the FDA regarding the FDA's process related to publishing bioequivalence guidances;
- An sNDA for Vancocin Capsules claiming a three-year marketing exclusivity;
- A lawsuit challenging the FDA's document production in response to ViroPharma's Freedom of Information Act document requests;
- A lawsuit challenging the FDA's in vitro dissolution guidance for another generic drug; and
- A lawsuit challenging the FDA's response to ViroPharma's Citizen Petition and related amendments and supplements, and the FDA's approval of generic Vancocin Capsules.

50. ViroPharma was well aware that it needed supporting clinical data to have any chance of persuading the FDA to require in vivo clinical endpoint studies to demonstrate bioequivalence. For example, even before it filed its citizen petition, Dr. Fleischer told ViroPharma that a citizen petition "is not a very convincing 'story' without data and references." Two other consultants observed that ViroPharma had failed to persuade any of the sixteen expert members of the Advisory Committee because ViroPharma did not provide any clinical data supporting its theoretical scientific arguments.

51. Notwithstanding this consistent advice from paid industry consultants, ViroPharma continued to submit filing after filing without any supporting clinical data. This practice continued even after the Advisory Committee unanimously rejected ViroPharma's position. Instead, ViroPharma repeated arguments that it had previously made, raised issues or arguments it could have raised earlier, submitted filings whose success it characterized as a "long shot," and made requests that the FDA would later deem an "improper use of the citizen petition process."

52. In addition to ViroPharma's formal filings with the FDA, ViroPharma raised its objections to the FDA's in vitro dissolution guidance for generic Vancocin Capsules through dozens of telephone calls, emails, and letters to various FDA offices and divisions. Many of ViroPharma's emails and letters to the FDA repeated issues it raised in its filings.

53. While ViroPharma understood that its petitioning campaign was unlikely to succeed in persuading the FDA to revise its bioequivalence guidance, it also learned that its petitioning was obstructing and delaying the FDA's approval of generic Vancocin Capsules. Consultants told ViroPharma that:

- "[t]actics" like filing petitions and lawsuits "[b]efore generic approvals . . . slow them down;"
- the FDA was resource-constrained and "overload[ed]" with a "tremendous number" of citizen petitions and that the FDA preferred to respond to citizen petition filings before or at the same time as approval of a pending application for a generic drug;
- the FDA was likely to approve generic Vancocin Capsules without requiring in vivo clinical endpoint studies, but that generic applications for Vancocin Capsules were "in limbo" because of ViroPharma's petitioning; and
- the FDA's clinical advisors appeared to have ruled against ViroPharma's Citizen Petition and that "the only thing holding up final approval of a Vancocin generic is the pending decision on ViroPharma's Citizens [sic] Petition."

A. March 2006 to March 2007: ViroPharma Begins Its Sham Petitioning Campaign to Obstruct and Delay the FDA's Approval of Generic Vancocin Capsules.

54. On March 17, 2006, ViroPharma submitted its initial citizen petition filing ("Citizen Petition Filing 1") to the FDA. ViroPharma's Citizen Petition Filing 1 requested that the FDA stay the approval of any ANDA for generic Vancocin Capsules and argued that in vitro dissolution testing was inappropriate for these products. ViroPharma did not detail or submit clinical support for its scientific argument. Instead, it indicated it would "shortly submit scientific evidence."

55. On March 30, 2006, ViroPharma filed an amendment to its citizen petition ("Citizen Petition Filing 2") to request a stay of approval of certain branded drugs similar to

Vancocin Capsules. ViroPharma, however, did not include or submit any clinical support. ViroPharma repeated that it would "shortly submit scientific evidence."

56. On May 31, 2006, ViroPharma submitted a third filing to its citizen petition docket ("Citizen Petition Filing 3"). In this filing, ViroPharma set forth legal and procedural objections to the FDA's in vitro dissolution guidance for generic Vancocin Capsules. ViroPharma stated that it "anticipates filing additional documents, at least one of which will detail how [the FDA Office of Generic Drugs'] new standard is unsupported as a matter of science."

57. On June 30, 2006, after receiving from a consultant a "Generic Management Plan" for Vancocin Capsules, which suggested "[t]actics" such as filing "petitions" and "lawsuits" "[b]efore generic approvals to slow them down," ViroPharma submitted its fourth citizen petition filing ("Citizen Petition Filing 4"). Despite its promise to submit scientific evidence, ViroPharma provided only theoretical and unsupported scientific arguments.

58. In its Citizen Petition Filing 4, ViroPharma argued that applicants for generic Vancocin Capsules should conduct clinical endpoint studies similar to those submitted with an NDA. Notwithstanding the fundamental public policy and scientific principle that testing on human subjects should be avoided whenever possible and the fact that the NDA for Vancocin Capsule did not include clinical endpoint studies, ViroPharma argued for clinical endpoint studies of several hundred hospitalized CDAD patients to compare the safety and efficacy of generic Vancocin Capsules, Vancocin Capsules, and a placebo. Without any data or clinical studies, ViroPharma made three theoretical arguments for requiring generics to conduct clinical endpoint studies:

a. First, ViroPharma claimed that various characteristics of a diseased patient's gastrointestinal tract could affect the dissolution and performance of generic Vancocin Capsules. But ViroPharma did not provide any clinical data showing that the dissolution and performance of generic Vancocin Capsules in diseased patients was different from branded Vancocin Capsules.

b. Second, ViroPharma argued that generic Vancocin Capsules could, "[a]lthough uncommon," be absorbed in diseased patients and, if absorbed, could cause safety concerns. ViroPharma did not, however, cite any such incidents of systemic absorption related to generic Vancocin Capsules or whether, even if they did occur, such incidents actually caused any safety issues.

c. Third, ViroPharma questioned the FDA's assumption that Vancocin Capsules were rapidly dissolving and stated that Vancocin Capsules did not fit squarely within a specific definition of dissolution. In making this argument, ViroPharma ignored Eli Lilly's assertion in its NDA that Vancocin Capsules were rapidly dissolving, a basis for the FDA's original approval of Vancocin Capsules in 1986.

59. In July 2006, around the time ViroPharma submitted Citizen Petition Filing 4, a consultant reported to ViroPharma that, based on his interviews of approximately thirty industry participants, the FDA would likely approve generic Vancocin Capsules without in vivo clinical endpoint studies. He also advised that the FDA's in vitro dissolution guidance for generic Vancocin Capsules would generate significant interest in bringing generic Vancocin Capsules to market.

60. A few months later, in an October 2006 report to ViroPharma, the consultant confirmed that at least one generic company had filed an ANDA for generic Vancocin Capsules and expected approval by the end of 2007.

61. In a third report to ViroPharma in March 2007, the same consultant repeated his view that the FDA would waive clinical trials for ANDAs for Vancocin Capsules and added that ANDAs for generic Vancocin Capsules appeared to be "in limbo" as a result of ViroPharma's petitioning. He wrote that the FDA was "overloaded[ed]" with a "tremendous number" of citizen petitions, and its preference was to respond to citizen petitions before or at the time of generic approval.

B. March 2007 to July 2008: ViroPharma Continues Its Repetitive, Serial, and Meritless Petitioning with Six More Filings to the FDA.

62. On March 16, 2007, ViroPharma submitted its fifth citizen petition filing ("Citizen Petition Filing 5"). In this filing, ViroPharma repeated its argument that diseased gastrointestinal tracts might differ from healthy gastrointestinal tracts and those differences might cause generic Vancocin Capsules to dissolve and perform differently from Vancocin Capsules in diseased gastrointestinal tracts. As in Citizen Petition Filing 4, ViroPharma did not submit clinical data supporting its argument, but stated it had initiated a study to compare the gastrointestinal tracts of diseased patients and healthy subjects and would submit the results of this study to the FDA once they were available. ViroPharma never submitted any data and did not inform the FDA that it later abandoned the study.

63. ViroPharma submitted its sixth and seventh citizen petition filings on May 17, 2007 ("Citizen Petition Filing 6") and December 30, 2007 ("Citizen Petition Filing 7"). These two filings related to other locally-acting drugs for which the FDA had allowed in vitro

dissolution testing to prove bioequivalence. ViroPharma argued that those guidances demonstrated broader institutional problems at the FDA.

64. On January 7, 2008, ViroPharma met with the FDA and repeated its arguments against accepting in vitro dissolution data with generic Vancocin Capsules applications. When the FDA described the approval of the NDA for Vancocin Capsules, ViroPharma asserted that clinical endpoint studies were conducted with Vancocin Capsules, but the studies may not have been submitted to the FDA. ViroPharma never substantiated this claim.

65. Following the January 7, 2008, meeting with the FDA, ViroPharma submitted its eighth citizen petition filing on January 11 ("Citizen Petition Filing 8"). In this filing, ViroPharma raised concerns about the FDA's process of disseminating its bioequivalence guidance. In May 2007, the FDA had announced its new process of disseminating bioequivalence guidance, under which the FDA would publish draft guidance and allow for a comment period. ViroPharma's eighth citizen petition filing was duplicative of a public comment filing that ViroPharma had submitted five months earlier, on August 29, 2007, in response to the FDA's May 2007 announcement.

66. On January 30, 2008, ViroPharma submitted its ninth citizen petition filing ("Citizen Petition Filing 9"). In this filing, ViroPharma repeated issues it had already presented at its January 7, 2008, meeting with the FDA.

67. Meanwhile around January 2008, ViroPharma's Vice President of Strategic Initiatives drafted a document entitled "Strategic Initiatives - 2008." This document designated Vancocin Capsules as ViroPharma's "first priority." It also referred to "[r]egulatory" methods as a way to "[e]xtend exclusivity for existing compounds" and specified "Additional C[itizen]

P[etition]s etc" as a method. ViroPharma's Vice President of Strategic Initiatives signed and submitted most of ViroPharma's filings to the FDA from this point forward.

68. A few months later, in June 2008, ViroPharma received competitive intelligence that the FDA was nearing generic approval. ViroPharma retained a consulting firm to examine what approach the FDA would take regarding the use of clinical endpoint studies for generic approval. Like its previous consultant, the new consulting firm advised ViroPharma that the "FDA will not require clinical bioequivalence trials for approval of an AB-rated generic Vancocin" (emphasis in original). This consulting firm also informed ViroPharma that clinical experts at the FDA had already rejected the arguments ViroPharma presented. The consultants specified that "the only thing holding up final approval of a Vancocin generic is the pending decision on ViroPharma's Citizen Petition." ViroPharma's consultants also noted that there were as many as nine generic applicants, and a high probability the FDA would approve numerous ANDAs. They could not predict, however, when the generics would actually be approved due to ViroPharma's ongoing efforts to delay entry.

69. On July 25, 2008, ViroPharma filed its tenth citizen petition filing ("Citizen Petition Filing 10"). In this filing, ViroPharma opposed the FDA's in vitro dissolution guidance regarding Precose, another locally acting gastrointestinal drug, and the FDA's response to a related citizen petition in May 2008. In that response, the FDA explained that it had the authority under 21 C.F.R. § 320.24 to accept in vitro dissolution studies to determine bioequivalence with Precose and recommended in vitro dissolution testing for generic Precose if it, including the inactive ingredients, was both quantitatively and qualitatively identical ("Q1Q2 same") to Precose. ViroPharma asserted that the FDA's rejection of the Precose citizen petition would influence the FDA's response to ViroPharma's Citizen Petition.

C. July 2008 to December 2008: The FDA Clarifies That In Vitro Dissolution Data May Establish Bioequivalence for Vancocin Capsules If Generic Versions Are "Q1Q2 Same."

70. In July 2008, the FDA convened a second public meeting of the Advisory Committee to discuss the bioequivalence methods for locally-acting gastrointestinal drugs. Although this meeting was to focus on locally-acting gastrointestinal drugs with low solubility, the Advisory Committee also discussed those with high solubility, like Vancocin Capsules. During this meeting, the FDA presented and discussed, *inter alia,* Q1Q2 sameness. The FDA opined that, when the generic drug is Q1Q2 same to the branded drug, highly soluble, and formulated as an immediate-release drug, bioequivalence can be demonstrated by in vitro dissolution. ViroPharma consultants and representatives of Akorn also presented their views at this meeting.

71. In December 2008, the FDA elaborated further on its in vitro dissolution guidance for generic Vancocin Capsules. It clarified that a generic drug application could use in vitro dissolution data to establish bioequivalence to Vancocin Capsules if the generic version was Q1Q2 same as Vancocin Capsules. The FDA published this draft guidance for public comment pursuant to the FDA's new process (announced in May 2007) for publishing bioequivalence guidance.

72. The FDA also noted that, although Vancocin Capsules might not fit squarely within a specific definition of rapid dissolution, the product dissolved rapidly enough to be in solution hours before it reaches the site of action, the lower gastrointestinal tract. The FDA also explained that, even if the patient population has variable gastrointestinal pH or transit times, similar dissolution profiles would ensure that the generic and branded Vancocin Capsules are bioequivalent within each individual patient. The FDA invited public comment for sixty days and agreed to consider comments before responding to ViroPharma's citizen petition filings.

D. December 2008 to June 2009: ViroPharma Begins Filing Public Comments on FDA's Guidance and Continues Submitting Citizen Petition Filings.

73. Despite having already made ten citizen petition filings over a two and one-half year period, on December 19, 2008, ViroPharma requested that the FDA extend the initial public comment period of sixty days for an additional sixty days ("Public Comment Filing 1"). The FDA extended the public comment period for an additional thirty days to March 19, 2009.

74. On February 27, 2009, ViroPharma asked for another extension after the FDA updated some of the data in its guidance ("Public Comment Filing 2"). The FDA denied ViroPharma's second extension request.

75. On March 18, 2009, a day before the expiration of the public comment period to the FDA's in vitro dissolution guidance for generic Vancocin Capsules, ViroPharma submitted identical sixty-five page filings in both the citizen petition and public comment dockets ("Citizen Petition Filing 11" and "Public Comment Filing 3"). In these filings, ViroPharma repeated, again without supporting clinical data, the same three theoretical scientific objections it had presented on June 20, 2006, in Citizen Petition Filing 4.

76. ViroPharma also added a new theoretical scientific objection in Citizen Petition Filing 11 and Public Comment Filing 3. ViroPharma claimed, for the first time, that Vancocin Capsules contained a previously unrevealed "trade secret" inactive ingredient that might affect its dissolution or performance. Although ViroPharma knew of this inactive ingredient since 2004, when it acquired Vancocin Capsules from Eli Lilly, it did not include this claim in Citizen Petition Filing 1 or any of its other filings before Citizen Petition Filing 11 and Public Comment Filing 3. ViroPharma also failed to include any supporting clinical data showing that the inactive ingredient affected the dissolution or performance of Vancocin Capsules.

77. In Citizen Petition Filing 11 and Public Comment Filing 3, ViroPharma also claimed that "[i]nitial data" from its study of gastrointestinal tracts of patients with CDAD and healthy volunteers substantiated its contention that CDAD patients do not exhibit the same gastrointestinal physiological characteristics as those of healthy volunteers. ViroPharma claimed that "[t]he results of this sentinel study will provide valuable data," but it never submitted any data from the study and never informed the FDA that it later abandoned the study.

78. On April 3, 2009, ViroPharma filed its fourth public comment ("Public Comment Filing 4"). ViroPharma repeated its previous objection that the FDA's in vitro dissolution guidance was modeled on a healthy or normal gastrointestinal tract. It asserted, again without clinical supporting data, that "[a]s ViroPharma has discussed repeatedly over the last three years, the diseased GI environment of Vancocin patients is profoundly different from the conditions found in the healthy GI."

79. A month later, on May 18, 2009, ViroPharma submitted another pair of identical submissions, its twelfth citizen petition ("Citizen Petition Filing 12") and fifth public comment filing (Public Comment Filing 5). Again, ViroPharma argued that the healthy gastrointestinal tract was not the appropriate model to measure bioequivalence. ViroPharma argued that the FDA was wrong to conclude that the site of action for CDAD was in the lower gastrointestinal tract, citing earlier case reports of patients who developed CDAD in their small intestines. ViroPharma failed to explain how the case reports were inconsistent with the FDA's conclusion that the site of action is the lower gastrointestinal tract (where most of the small intestine is located) or how these reports were related to the bioequivalence of generic Vancocin Capsules.

E. August 2009: ViroPharma Repeats Its Unsupported Scientific Arguments to the Advisory Committee; the Advisory Committee Unanimously Supports the FDA's In Vitro Dissolution Guidance.

80. In the summer of 2009, the FDA announced that it was convening another meeting of the Advisory Committee. This meeting was to discuss and for Advisory Committee members to vote on the FDA's in vitro dissolution guidance for generic Vancocin Capsules.

81. In anticipation of that meeting, on June 30, 2009, ViroPharma submitted a brief to the Advisory Committee detailing its scientific objections to the FDA's in vitro dissolution guidance for generic Vancocin Capsules and why it thought clinical endpoint studies were necessary. Among other things, ViroPharma repeated four theoretical issues or arguments, each of which it had raised within its previous eighteen submissions to the FDA:

a. Gastrointestinal tracts of patients with CDAD might differ from healthy people and those differences might impact the dissolution and performance of generic Vancocin Capsules;

b. Certain CDAD patients may systemically absorb oral vancomycin hydrochloride, which might cause side effects;

c. The FDA should reconsider its in vitro dissolution guidance given the seriousness of CDAD; and

d. Inactive ingredients can act differently and affect dissolution or systemic absorption.

82. On July 8, 2009, the FDA submitted a brief to the Advisory Committee. In it, the FDA detailed its rationale for permitting generics to use in vitro dissolution testing to establish bioequivalence to Vancocin Capsules, noting that it had originally approved the NDA for Vancocin Capsules "based on dissolution data instead of clinical [endpoint] studies."

83. On July 31, 2009, ViroPharma responded to the FDA's briefing with another set of identical filings in both the citizen petition and public comment dockets ("Citizen Petition Filing 13" and "Public Comment Filing 6"). In these filings, ViroPharma disputed the FDA's assertion that it had approved Vancocin Capsules based on in vitro dissolution data. ViroPharma's contemporaneous internal documents, however, contradict this position. In its "Regulatory Development Strategy Plan" for Vancocin Capsules, ViroPharma stated that the approval of Vancocin Capsules was indeed based on in vitro dissolution, specifying that "[i]n vitro dissolution information was considered essential for demonstrating efficacy." ViroPharma added "[r]eviewers concluded from dissolution tests that vancomycin hydrochloride was released quickly from the Capsules formulation and therefore would be efficacious."

84. On August 3, 2009, the FDA submitted an addendum to its brief to the Advisory Committee. In the addendum, the FDA affirmed once again that it had approved branded Vancocin Capsules "based on dissolution data instead of clinical [endpoint] studies."

85. On August 4, 2009, the FDA convened the Advisory Committee to publicly discuss and vote on the FDA's in vitro dissolution guidance for generic Vancocin Capsules. The Advisory Committee comprised sixteen independent experts knowledgeable in the fields of pharmaceutical sciences, clinical pharmacology, and gastrointestinal diseases from academia, non-profit organizations, and hospitals. After the presentations, including ViroPharma's, and a related public discussion, each independent expert on the Advisory Committee was asked whether he or she accepted the FDA's recommendation to accept demonstration of bioequivalence through in vitro dissolution data if generic Vancocin Capsules were Q1Q2 same. The Advisory Committee voted unanimously, 16-0, in favor of the FDA's in vitro dissolution guidance.

F. ViroPharma's Consultants Advise It That the Advisory Committee Unanimously Rejected Its Arguments Due to Its Failure to Provide Supporting Data.

86. Following the August 2009 Advisory Committee meeting and vote, Dr. Ciaran Kelly, a ViroPharma consultant and presenter at the Advisory Committee meeting, confirmed to ViroPharma that it did not get any votes because it failed to provide any supporting clinical data. Dr. Kelly told ViroPharma that, "I don't see what ViroPharma could have done better to change the outcome given the available data (or lack thereof)." Dr. Kelly also stated that "[t]he FDA successfully neutralized the powerful and well-received 'altered gut physiology' and 'site of action' arguments simply by saying that it held for Vancocin and generics alike. *Annoyingly true* – it was raised at mock AdCom *but we had no answer (except doubt and uncertainty)* and it was one of our best cards so we correctly played it!" (emphasis added).

87. The other ViroPharma speaker and consultant at the August 2009 Advisory Committee meeting, Patrick Noonan, Ph.D., gave ViroPharma similar feedback. Following the Advisory Committee meeting and vote, Dr. Noonan emailed ViroPharma employees that he was convinced that "companies need to bring data in to make their point . . . our lack of data only played into [the opposing] argument."

G. October 2009 to December 2009: Despite the Advisory Committee's Unanimous Vote and the Feedback from ViroPharma's Consultants, ViroPharma Continues Its Sham Petitioning Campaign.

88. Despite the Advisory Committee's unanimous vote in support of the FDA's in vitro dissolution guidance and ViroPharma's knowledge that it needed clinical data to have any chance of persuading the FDA otherwise, ViroPharma submitted twenty-three more filings to the FDA, all without providing any supporting clinical data. In the year following the Advisory Committee's unanimous vote, ViroPharma filed seventeen more submissions with the FDA,

repeating previous arguments, requesting broad procedural actions, and demanding answers to what the FDA deemed "improper" interrogatory-style questions.

89. On October 6, 2009, ViroPharma submitted its fourteenth citizen petition and seventh public comment filing ("Citizen Petition Filing 14" and "Public Comment Filing 7"). ViroPharma repeated, as it had in its Citizen Petition Filing 11 and Public Comment Filing 3, its claim that Vancocin Capsules contain a trade secret inactive ingredient and thus generic formulations would not likely contain that ingredient. ViroPharma added that it was testing generic formulations in foreign countries for the trade secret inactive ingredient and that none of the generic formulations it claimed to have tested contained that ingredient. It did not include any clinical data showing that the trade secret inactive ingredient affected dissolution or performance. In its Citizen Petition Filing 14 and Public Comment Filing 7, ViroPharma also repeated that Vancocin Capsules did not fit squarely into a specific definition of rapid dissolution despite the FDA's public response to this argument in December 2008.

90. On November 25, 2009, ViroPharma submitted its fifteenth citizen petition and eighth public comment filing ("Citizen Petition Filing 15" and "Public Comment Filing 8"). In these filings, ViroPharma requested sixteen additional actions from the FDA, "the grounds for which have either been explained in previous filings by ViroPharma or have arisen recently." Many of the sixteen additional actions asked the FDA to take procedural steps like withdrawing the FDA's in vitro dissolution guidance for generic Vancocin Capsules and providing public notice that the recommendations were promulgated in violation of agency procedure and without legal authority.

91. On December 2, 2009, ViroPharma amended Citizen Petition Filing 15 and Public Comment Filing 8 with its sixteenth citizen petition and ninth public comment filing ("Citizen

Petition Filing 16" and "Public Comment Filing 9"). Those filings merely attached as exhibits to the previous filings copies of documents "not otherwise readily publicly available," which were documents that the FDA had previously provided to ViroPharma.

92. A little more than two weeks later, on December 18, 2009, ViroPharma submitted another filing, its seventeenth citizen petition and tenth public comment filing ("Citizen Petition Filing 17" and "Public Comment Filing 10"). ViroPharma repeated its argument about the trade secret inactive ingredient from its Citizen Petition Filing 14 and Public Comment Filing 7. ViroPharma added that it had completed testing a number of generic formulations from foreign countries and none of them contained the trade secret inactive ingredient. But ViroPharma did not submit any clinical data showing that the trade secret inactive ingredient affected the safety or efficacy of the drug.

H. January 2010 to March 2010: ViroPharma Files Improper Interrogatories to the FDA.

93. Starting in January 2010, ViroPharma shifted to a new tactic, asking the FDA a litany of fact-specific questions, analogous to interrogatories in civil discovery. The FDA subsequently deemed ViroPharma's tactic an "improper use of the citizen petition process." ViroPharma submitted two sets of such improper filings. In the first filing, submitted as both a citizen petition filing and a public comment filing on January 15, 2010, ViroPharma presented sixty-three interrogatory-type questions, many with sub-parts, after receiving and reviewing the FDA's internal documents ("Citizen Petition Filing 18" and "Public Comment Filing 11"). Many of the questions pertained to specific documents or the actions of individual FDA employees.

94. On March 25, 2010, ViroPharma made another pair of similarly improper filings ("Citizen Petition Filing 19" and "Public Comment Filing 12"). ViroPharma asked forty additional fact-specific questions such as "[h]ow does [the Office of Generic Drugs] determine

which [Center for Drug Evaluation and Research] divisions should be consulted on [bioequivalence] methods, and who is responsible for making these consultation decisions?"

I. April 2010 to December 2011: ViroPharma Steps Up Its Sham Petitioning Campaign As Generic Entry Nears.

95. In April 2010, ViroPharma heard that Akorn was preparing to enter the market imminently. Akorn reportedly informed pharmaceutical wholesale distributors that it expected to have generic Vancocin Capsules available for sale by April 27, 2010.

96. On April 23, 2010, just days before the anticipated date of generic entry, ViroPharma filed an sNDA for Vancocin Capsules and claimed it was entitled to a three-year period of marketing exclusivity, during which the FDA could not approve any generic Vancocin Capsules.

97. ViroPharma understood the dubious nature of its claim to marketing exclusivity. ViroPharma had described its claim as a "long shot" to its Board of Directors, and its Chief Scientific Officer described it as a "Hail Mary pass."

98. On June 25, 2010, ViroPharma filed its twentieth citizen petition and thirteenth public comment filing ("Citizen Petition Filing 20" and "Public Comment Filing 13"). In these identical filings, ViroPharma criticized the FDA for recommending and using a particular in vitro dissolution method, even though ViroPharma had known about the recommendation since 2006 and, in fact, had used the same method in testing Vancocin Capsules in 2006. ViroPharma also asked additional fact-specific interrogatory-style questions that the FDA subsequently deemed an "improper use of the citizen petition process."

99. Around the time of its Citizen Petition Filing 20 and Public Comment Filing 13, ViroPharma heard from multiple sources that Akorn would begin shipping generic Vancocin Capsules in days.

100. On July 20, 2010, less than a month after submitting its prior pair of filings, ViroPharma submitted yet another pair of identical filings ("Citizen Petition Filing 21" and "Public Comment Filing 14"). ViroPharma reiterated its criticism of the particular in vitro dissolution method the FDA (and it) had used. ViroPharma also repeated its concern that generic products did not contain ViroPharma's trade secret inactive ingredient.

101. On December 22, 2010, ViroPharma submitted its twenty-second citizen petition and fifteenth public comment filing ("Citizen Petition Filing 22" and "Public Comment Filing 15"). ViroPharma once again maintained that clinical endpoint studies were the only method on which bioequivalence for generic Vancocin Capsules could be established, and that applications for generic Vancocin Capsules must contain clinical endpoint bioequivalence data to be approvable. ViroPharma persisted in making this argument despite the August 2009 unanimous vote of the Advisory Committee in support of the FDA's in vitro dissolution guidance for generic Vancocin Capsules. ViroPharma again did not provide any supporting clinical data.

102. ViroPharma submitted its next identical pair of filings ("Citizen Petition Filing 23" and "Public Comment Filing 16") on November 21, 2011. ViroPharma submitted an animal study comparing the efficacy of branded and generic intravenous vancomycin, even though it had internally questioned the relevance of this study a year earlier, because the animal study concerned intravenous vancomycin, a drug with a different route of administration, mechanism, and indication than Vancocin Capsules.

103. On December 22, 2011, ViroPharma submitted its final pair of identical filings ("Citizen Petition Filing 24" and "Public Comment Filing 17"). ViroPharma again claimed entitlement to a three-year period of marketing exclusivity. The FDA agreed to some of ViroPharma's requests concerning labeling, but ViroPharma had not sought approval of, and the

FDA had not approved, a new use of Vancocin Capsules, which was necessary for eligibility to the three-year period of marketing exclusivity.

J. April 2012: The FDA Rejects All of ViroPharma's Scientific Challenges as Unsupported and Lacking Merit.

104. On April 9, 2012, the FDA provided a lengthy and comprehensive rejection of ViroPharma's citizen petition filings, including each supplement and amendment, and public comment filings. In an eighty-five page, single-spaced response, the FDA found that "ViroPharma's scientific challenges to the bioequivalence recommendation lack merit" and were "unsupported." It also rejected each of ViroPharma's legal arguments.

105. The FDA also denied all of ViroPharma's procedural challenges, except to the extent that ViroPharma requested and was provided notice of and an opportunity to comment on FDA's in vitro dissolution guidance for generic Vancocin Capsules and the related data.

106. The FDA added that ViroPharma's tactics for challenging the FDA's process, specifically ViroPharma's interrogatory-type questions to the FDA, were "an improper use of the citizen petition process."

107. The FDA also rejected ViroPharma's claim to a three-year marketing exclusivity based on its sNDA. On the same day, April 9, 2012, the FDA approved three ANDAs for generic Vancocin Capsules, including Akorn's ANDA.

K. ViroPharma Files Three Lawsuits Against the FDA.

108. In addition to its repetitive filings to the FDA, ViroPharma also filed three lawsuits against the FDA: (1) a December 2008 challenge to the FDA's production to ViroPharma's Freedom of Information Act ("FOIA") requests for documents related to Vancocin Capsules and generic Vancocin Capsules; (2) a September 2010 challenge to the FDA's bioequivalence guidance for generic Precose; and (3) an April 2012 challenge to the FDA's

generic approvals and response to ViroPharma's citizen petition filings, public comment filings and claim for marketing exclusivity.

109. ViroPharma did not prevail in any of its three lawsuits against the FDA. The lawsuits were either dismissed by the courts or withdrawn by ViroPharma.

1. December 2008: ViroPharma Files a Flawed FOIA Suit Against the FDA.

110. On March 21, 2006,ViroPharma submitted a FOIA request to the FDA. On December 16, 2008, the same day the FDA published its in vitro dissolution guidance for generic Vancocin Capsules, ViroPharma submitted a second FOIA request to the FDA and sued the FDA.

111. In April 2010, the FDA moved for summary judgment on the grounds that it had fulfilled its FOIA obligations, and included a list of withheld documents. ViroPharma cross-filed a motion for summary judgment requesting an *in camera* review of the withheld documents and arguing that the FDA had acted in bad faith.

112. In March 2012, the district court denied ViroPharma's cross-motion for summary judgment in full. As for the FDA's motion for summary judgment, the district court granted it in part and denied it in part. While the district court found that the FDA properly withheld certain information and documents, it required the FDA to supplement its list of withheld documents with additional information. The FDA did so in May 2012. In June 2012, ViroPharma agreed to withdraw its lawsuit.

2. September 2010: ViroPharma Files an Unsuccessful Suit Challenging the FDA's In Vitro Dissolution Guidance for an Entirely Different Drug That ViroPharma Does Not Manufacture or Sell.

113. ViroPharma filed its second lawsuit against the FDA on September 10, 2010, around the time it was hearing reports of Akorn's imminent entry. In this lawsuit, ViroPharma

challenged the FDA's in vitro dissolution guidance for generic Precose, a drug used in the management of type two diabetes that ViroPharma did not own or market and was not related to Vancocin Capsules. In a November 2007 citizen petition, Cobalt, a manufacturer of generic Precose, had opposed the FDA's guidance for generics to use in vitro dissolution data to establish bioequivalence to Precose. In May 2008, the FDA denied Cobalt's citizen petition and approved two more generic Precose applications. In July 2008, ViroPharma filed Citizen Petition Filing 10, challenging FDA's guidance for Precose and denial of Cobalt's citizen petition. Two years later, ViroPharma, who did not have any relationship to Cobalt or Precose, challenged the FDA's denial of Cobalt's citizen petition in court.

114. The district court dismissed ViroPharma's lawsuit, on the grounds that ViroPharma lacked standing. ViroPharma appealed the district court decision to the D.C. Circuit. In March 2012, the D.C. Circuit affirmed the dismissal after cancelling oral argument.

3. April 2012: ViroPharma Files an Unsuccessful Suit to Reverse the FDA's Approval of Generic Vancocin Capsules.

115. On April 13, 2012, following the FDA's detailed response to all of ViroPharma's citizen petition and public comment filings and the FDA's approval of generic competitors, ViroPharma sued the FDA and moved for a temporary restraining order and/or preliminary injunction against the FDA's approvals of generic Vancocin Capsules.

116. On April 25, 2012, the district court rejected ViroPharma's arguments and denied its motion, holding that ViroPharma was unlikely to establish that the FDA had erred in denying ViroPharma's Citizen Petition and approving ANDAs for generic Vancocin Capsules.

117. Months later, on January 9, 2013, the district court also denied ViroPharma's motion for summary judgment noting, "ViroPharma all but admits that it has presented no

substantially new arguments." The district court concurrently granted the FDA's motion to dismiss ViroPharma's complaint.

L. ViroPharma Made Forty-Six Filings Over Six Years.

118. ViroPharma's petitioning lasted over six years. The following table lists ViroPharma's forty-six filings and their filing dates:

	Filing	**Date**
1.	Citizen Petition Filing 1	March 17, 2006
2.	Citizen Petition Filing 2	March 30, 2006
3.	Citizen Petition Filing 3	May 31, 2006
4.	Citizen Petition Filing 4	June 30, 2006
5.	Citizen Petition Filing 5	March 16, 2007
6.	Citizen Petition Filing 6	May 17, 2007
7.	Public Comment Filing on FDA Process	August 29, 2007
8.	Citizen Petition Filing 7	December 30, 2007
9.	Citizen Petition Filing 8	January 7, 2008
10.	Citizen Petition Filing 9	January 30, 2008
11.	Citizen Petition Filing 10	July 25, 2008
12.	FDA Lawsuit 1	December 16, 2008
13.	Public Comment Filing 1	December 19, 2008
14.	Public Comment Filing 2	February 27, 2009
15.	Citizen Petition Filing 11	March 18, 2009
16.	Public Comment Filing 3	March 18, 2009
17.	Public Comment Filing 4	April 3, 2009
18.	Citizen Petition Filing 12	May 18, 2009
19.	Public Comment Filing 5	May 18, 2009
20.	Citizen Petition Filing 13	July 31, 2009
21.	Public Comment Filing 6	July 31, 2009
22.	Citizen Petition Filing 14	October 6, 2009
23.	Public Comment Filing 7	October 6, 2009
24.	Citizen Petition Filing 15	November 25, 2009
25.	Public Comment Filing 8	November 25, 2009
26.	Citizen Petition Filing 16	December 2, 2009
27.	Public Comment Filing 9	December 2, 2009
28.	Citizen Petition Filing 17	December 18, 2009
29.	Public Comment Filing 10	December 18, 2009
30.	Citizen Petition Filing 18	January 15, 2010
31.	Public Comment Filing 11	January 15, 2010
32.	Citizen Petition Filing 19	March 25, 2010
33.	Public Comment Filing 12	March 25, 2010

34.	Supplemental New Drug Application	April 23, 2010
35.	Citizen Petition Filing 20	June 25, 2010
36.	Public Comment Filing 13	June 25, 2010
37.	Citizen Petition Filing 21	July 20, 2010
38.	Public Comment Filing 14	July 20, 2010
39.	FDA Lawsuit 2	September 10, 2010
40.	Citizen Petition Filing 22	December 22, 2010
41.	Public Comment Filing 15	December 22, 2010
42.	Citizen Petition Filing 23	November 21, 2011
43.	Public Comment Filing 16	November 21, 2011
44.	Citizen Petition Filing 24	December 22, 2011
45.	Public Comment Filing 17	December 22, 2011
46.	FDA Lawsuit 3	April 13, 2012

M. ViroPharma Engaged In Repetitive and Serial Petitioning Without Regard to the Merits To Use the Petitioning Process To Delay Generic Competition.

119. ViroPharma's filings with the FDA and the courts were made without regard to the merits of the issues raised.

120. ViroPharma's forty-six filings failed to convince the FDA of its stated primary goal: to rescind the FDA's in vitro dissolution guidance for generic Vancocin Capsules and to require generic applicants to conduct clinical endpoint studies. The FDA rejected ViroPharma's scientific arguments and approved multiple generics based on the in vitro dissolution guidance and without clinical endpoint studies.

121. ViroPharma's successes, if any, regarded the publication and elaboration of the FDA's in vitro dissolution guidance for generic Vancocin Capsule in December 2008. Otherwise, ViroPharma's petitioning efforts were consistently unsuccessful. The FDA never changed its position that generic applicants whose product was Q1Q2 same as Vancocin Capsules could use in vitro dissolution data to establish bioequivalence.

122. All told, ViroPharma made 165 requests for administrative action in its citizen petition filings. The FDA denied or deemed improper the vast majority of ViroPharma's requests

for administrative action. Further, the FDA rejected ViroPharma's scientific arguments as "unsupported" and found them to "lack merit."

123. Sixteen independent scientists and doctors on the Advisory Committee also considered and rejected ViroPharma's scientific arguments. They voted 16-0 in favor of the FDA's in vitro dissolution guidance for generic Vancocin Capsules.

124. ViroPharma's other proceedings also were unsuccessful. The FDA denied ViroPharma's claim for a three-year marketing exclusivity.

125. ViroPharma also did not prevail in any of its lawsuits. The court dismissed two of ViroPharma's three lawsuits against the FDA, the Precose and Citizen Petition lawsuits. Further, ViroPharma withdrew its FOIA lawsuit against the FDA after the court denied ViroPharma's substantive motions.

126. ViroPharma's assertion that clinical endpoint studies are necessary for generic approval did not make sense. Clinical endpoint studies do not measure bioavailability or bioequivalence directly, and ViroPharma knew that Vancocin Capsules' approval was based on in vitro dissolution data, not clinical endpoint studies. A generic drug's approval process is intended to be abbreviated, not more onerous, than a branded drug's approval.

127. None of ViroPharma's filings to the FDA included supporting clinical data, despite the advice of multiple expert consultants to ViroPharma that it needed such data to have any chance of persuading the FDA. Unsurprisingly, the FDA ultimately rejected ViroPharma's scientific arguments as "unsupported."

128. ViroPharma continued to submit repetitive, serial, and meritless filings and arguments despite continued doubts and questions about its filings and arguments. ViroPharma

made these submissions knowing that its filings were delaying generic approval and unlikely to persuade the FDA.

129. ViroPharma continued its petitioning even though it understood that its theoretical and unsupported arguments would not convince the FDA to abandon its guidance on in vitro dissolution for generic Vancocin Capsules.

VIII. VIROPHARMA POSSESSED MONOPOLY POWER IN THE RELEVANT MARKET

130. The relevant product market is the market for Vancocin Capsules and its generic equivalents.

131. The relevant geographic market is the United States. FDA approval is required to market pharmaceuticals to U.S. consumers. As a result, drugs sold outside of the United States are not viable competitive alternatives for U.S. consumers.

132. ViroPharma exercised monopoly power in the relevant market at least until the date of generic entry in April 2012. At all times until generic entry, ViroPharma possessed a 100% share of the relevant market.

133. There is substantial direct evidence that ViroPharma exercised its monopoly power.

134. Direct evidence of ViroPharma's monopoly power include its demonstrated ability to control the pricing of Vancocin Capsules before generic entry and the effect of generic entry on Vancocin Capsules' price and sales.

135. Other drugs used to treat CDAD did not meaningfully constrain ViroPharma's pricing or sales of Vancocin Capsules, and were not substitutes for Vancocin Capsules. For example, by the time ViroPharma acquired Vancocin Capsules in 2004, generic metronidazole was already available and used off-label to treat patients with moderate CDAD. Despite the

availability of lower-priced generic metronidazole, ViroPharma successfully increased the price of Vancocin Capsules without losing sales. Between 2004 and 2011, ViroPharma more than tripled the average wholesale price of Vancocin Capsules from $6.38 to $24.61 for the 125 mg dosage strength and from $12.73 to $46.48 for the 250 mg dosage strength. Over that same period, however, ViroPharma's unit sales increased by close to 37% for the 125 mg strength and 39% for the 250 mg strength.

136. In addition, the entry of Dificid, a new branded drug to treat CDAD, in May 2011 did not have a constraining impact on Vancocin Capsules prices or sales. Indeed, by late 2011, after the commercial entry of Dificid, ViroPharma once again raised the price of Vancocin Capsules without losing significant unit sales. After the first three months of Dificid's market entry, ViroPharma increased the wholesale prices for both dosage strengths of Vancocin Capsules by approximately 6%. During that same time-period, the unit sales in the 125 mg strength increased by about 1% and the 250 mg strength decreased by less than 2%.

137. Moreover, because of its unique characteristics, Vancocin Capsules are not reasonably interchangeable with other medications used to treat CDAD. While other drugs, such as generic metronidazole, can be used off-label to treat moderate CDAD, Vancocin Capsules are reserved for more severe cases or as a second-line treatment after the failure of metronidazole.

138. ViroPharma's internal documents demonstrate that it recognized that Vancocin Capsules were a "sole source item" in that it faced "no competition in its current space" as a life-saving drug for CDAD. As a ViroPharma executive testified, Vancocin Capsules were "non-substitutable" until generic versions of Vancocin Capsules entered the market.

139. ViroPharma predicted a dramatic decline in the average price of Vancocin Capsules following generic entry. Additionally, ViroPharma expected that competition from a

generic product would lead to a rapid and dramatic decline in its Vancocin Capsules revenues. For example, as part of its due diligence before acquiring Vancocin Capsules, ViroPharma forecasted that branded Vancocin Capsules would experience a 50% reduction in sales revenue a year after generic entry.

140. The data available since the entry of generic Vancocin Capsules confirm the unique competitive impact of such entry on Vancocin Capsules sales and prices. When generic Vancocin Capsules entered the market in April 2012, the average price of branded and generic Vancocin Capsules decreased by 17% after three months. Furthermore, the unit sales of the 125 mg and 250 mg dosage strengths of branded Vancocin Capsules decreased by approximately 65% and 69%, respectively, three months after generic entry.

141. If ViroPharma were already facing robust competition to Vancocin Capsules before generic entry, then generic competition to Vancocin Capsules would not have eroded the sales volume of branded Vancocin Capsules or affected the price of Vancocin Capsules so rapidly and dramatically.

142. Substantial barriers to entry exist in the Vancocin Capsules market. Potential new branded drug competitors need to conduct expensive clinical trials to obtain FDA approval. Potential sellers of generic versions of Vancocin Capsules also face substantial barriers to entry, including the need to obtain FDA approval.

IX. VIROPHARMA'S CONDUCT HARMED COMPETITION AND CONSUMERS

143. ViroPharma willfully maintained and extended its monopoly power as to Vancocin Capsules by submitting repetitive, serial, and meritless filings to the FDA and courts. ViroPharma's repetitive, serial, and meritless filings constitute wrongful and exclusionary conduct.

144. ViroPharma's repetitive, serial, and meritless petitioning harmed competition and consumer welfare by obstructing and delaying the FDA approval process for a generic version of Vancocin Capsules. ViroPharma was well aware of the FDA's practice to refrain from approving generic applications until it resolved any relevant, pending citizen petition filings and explicitly petitioned the FDA to stay the approval of any ANDA for generic Vancocin Capsules. Indeed, ViroPharma's own consultants had informed it, on numerous occasions, that the generic applications were "in limbo," and that "the only thing holding up final approval of a Vancocin generic is the pending decision on ViroPharma's Citizen Petition."

145. Each time the FDA was close to finalizing its response to ViroPharma's filings and contemporaneously approving generic Vancocin Capsules, ViroPharma would submit another filing, often raising issues that ViroPharma itself doubted or that it could have raised earlier and/or repeating issues raised earlier. ViroPharma's conduct effectively derailed the FDA's progress. For example:

- On December 16, 2008, the same day the FDA published its in vitro dissolution guidance for generic Vancocin Capsules, paving the way for generic entry, ViroPharma submitted a second FOIA request to the FDA and sued the FDA;
- On March 18, 2009, one day before the end of the public comment period, during which the FDA had postponed any response to ViroPharma's citizen petition pending its receipt and review of comments, ViroPharma submitted a sixty-five page filing in both the citizen petition and public comment dockets;
- ViroPharma waited three years after its initial filing to submit its claim to the FDA regarding its supposed "trade secret ingredient," which ViroPharma had known about for years, but had never previously raised;

- ViroPharma submitted its sNDA in April 2010, the same month that ViroPharma learned that Akorn was informing drug wholesale distributors that it planned to have generic Vancocin Capsules available for sale by April 27;
- ViroPharma did not object to the recommended dissolution method until June 2010, when it heard renewed reports of Akorn's imminent entry, even though the FDA had specified the dissolution method years ago in 2006, and ViroPharma itself had used that method; and
- Six months later, after hearing renewed reports of Akorn's imminent entry, ViroPharma filed a second lawsuit against FDA relating to Precose, for which it had no legal standing and for which it had already submitted a related citizen petition filing two years earlier.

ViroPharma's strategically-timed claims and additional filings had the effect of impeding the FDA's response to ViroPharma's claims and approval of generic Vancocin Capsules.

146. Akorn submitted its ANDA for generic Vancocin Capsules on March 5, 2007. By April 20, 2007, the FDA had designated Akorn's ANDA for expedited or priority review. Strides and Watson also submitted generic Vancocin Capsules applications in 2007. In July 2010, an FDA employee from the Office of Generic Drugs, the FDA office that approves generic applications, informed Akorn that its generic application was ready for approval but that ViroPharma's citizen petition filings have to be resolved for the ANDA to be approved.

147. Absent ViroPharma's exclusionary conduct, generic entry would have occurred earlier than April 9, 2012—the date that the FDA finally resolved ViroPharma's Citizen Petition and its numerous supplements and amendments and approved three generic applications for Vancocin Capsules. Indeed, absent ViroPharma's exclusionary conduct, generic entry likely

would have occurred by July 2010 – when Akorn's ANDA was otherwise ready for approval – or even earlier.

148. By impeding generic competition, ViroPharma's sham petitioning conduct denied consumers and other purchasers of Vancocin Capsules access to AB-rated generic versions of Vancocin Capsules that would offer the same therapeutic benefit as the branded drug, but at a significantly lower price.

149. Earlier entry of a generic product would have given consumers the choice between Vancocin Capsules and lower-priced generic substitutes for Vancocin Capsules. Many consumers would have chosen to purchase the lower-priced generic version instead of higher-priced Vancocin Capsules. In its contemporaneous forecasts, ViroPharma predicted that its Vancocin Capsules revenues would drop by 50% within the first year of generic entry. The actual data following generic entry shows an even more significant impact on ViroPharma's Vancocin Capsules sales—with ViroPharma losing almost 70% of its unit sales within the first three months. Had generic competition entered earlier than April 9, 2012, consumers would have saved hundreds of millions of dollars. By engaging in its exclusionary conduct, ViroPharma has enjoyed additional monopoly profits at the expense of consumers.

150. Absent an injunction, there is a cognizable danger that ViroPharma will engage in similar conduct causing future harm to competition and consumers. ViroPharma knowingly carried out its anticompetitive and meritless petitioning campaign to preserve its monopoly profits. It did so conscious of the fact that this conduct would greatly enrich it at the expense of consumers.

151. ViroPharma has the incentive and opportunity to continue to engage in similar conduct in the future. At all relevant times, ViroPharma marketed and developed drug products

for commercial sale in the United States, and it could do so in the future. Consequently, ViroPharma has the incentive to obstruct or delay competition to these or other products.

152. ViroPharma obtained the full benefit of its unlawful conduct concerning Vancocin Capsules.

COUNT I

MONOPOLIZATION

153. Plaintiff re-alleges and incorporates by reference the allegations in all of the preceding paragraphs.

154. ViroPharma's willful maintenance of its monopoly through a course of anticompetitive conduct, including submitting repetitive, serial, and meritless filings to the FDA and courts, constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

PRAYER FOR RELIEF

WHEREFORE, Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to issue a permanent injunction against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by Defendant's violations; therefore, the FTC requests that this Court, as authorized by 15 U.S.C. § 53(b), 15 U.S.C. § 26, and its own equitable powers, enter final judgment against Defendant on Count I, declaring, ordering, and adjudging:

1. That ViroPharma's course of conduct, including submitting repetitive, serial, and meritless filings with the FDA and courts, violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);

2. That Defendant is permanently enjoined from engaging in similar and related conduct in the future; and

3. That the Court grant such other equitable relief as the Court finds necessary, including restitution or disgorgement, to redress and prevent recurrence of Defendant's violations of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), as alleged herein.

Dated: February 7, 2017

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Respectfully Submitted,

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